ISRCTN10541688 https://doi.org/10.1186/ISRCTN10541688

Does the application of fluoride varnishes during pregnancy induce changes in fluoride concentrations in the saliva of pregnant women?

Submission date
14/06/2022

Recruitment status
No longer recruiting

Registration date
29/06/2022

Overall study status
Completed

Last Edited
15/07/2022

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
During pregnancy, there is a higher risk of getting oral diseases, like caries or periodontal disease. Likewise, certain oral diseases have been related to bad pregnancy outcomes (preeclampsia, preterm birth). A preventive program is necessary that allows pregnant women good control over their oral health and access to preventive methods. The aim of this study is to evaluate the differences in fluoride concentrations in the saliva of pregnant women after the use of three fluoride varnishes (Clinpro White Varnish 3M ESPE®, VOCO Profluorid Varnish®, and MI Varnish GC Tokio®).

Who can participate?
Healthy pregnant women between 16 and 31 weeks of gestation

What does the study involve?
Different questionnaires were used to collect information about sociodemographic background, hygienic habits, beliefs, and epidemiological indices, involving decayed, missing, and filled teeth scoring of those women who assisted in the preventive program between 2018 and 2019 that had already been set up in Clinica Odontológica Universitaria. In the first visit, we collected two samples of saliva (one before and one after the application of the fluoride varnish), and for further analysis, during the other visits (after 15, 30, and 45 days) we took one sample.

What are the possible benefits and risks of participating?
The main benefit pregnant woman can get from participating in the study is an improvement in their oral health and knowledge related to their oral health and their babies. There is no risk in participating.

Where is the study run from?
Clínica Odontológica Universitaria from Universidad de Murcia (Spain)

When is the study starting and how long is it expected to run for?
September 2018 to October 2022

Who is funding the study?
Universidad de Murcia (Spain)

Who is the main contact?
Miss Icíar Fernández Pizarro (Spain)
iciarfp@gmail.com

Contact information

Type(s)
Scientific

Contact name
Miss Iciar Fernández Pizarro

Contact details
Universidad de Murcia
Departamento de Dermatología
Estomatología
Radiología y Medicina física
Av. Marqués de los Vélez
Murcia
Spain
30008
+34 868888583
iciar.fernandez@um.es

Type(s)
Principal Investigator

Contact name
Prof Yolanda Martinez-Beneyto

ORCID ID
http://orcid.org/0000-0002-1523-9415

Contact details
Universidad de Murcia
Departamento de Dermatología
Estomatología
Radiología y Medicina física
Av. Marqués de los Vélez
Murcia
Spain
30008
+34 868888583
yolandam@um.es

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Fluoride varnish effects in fluoride concentration in saliva throughout pregnancy: Longitudinal Clinical Randomized Trial

Study objectives
The application of fluoride varnishes throughout pregnancy does not induce changes in fluoride concentrations in saliva in pregnant women

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/05/2019, Comité de Ética de Investigación (Research Ethics Commission) of Murcia University (Calle Santo Cristo 1, 30001, Murcia, Spain; +34 868 88 3614; comision.etica.investigacion@um.es), ref: 2265/2019

Study design
Longitudinal randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Fluoride concentration in saliva in pregnant women

Interventions

Pregnant women come to the Preventive Program recommended by their general practitioners. In the first visit, we take a sample of saliva before any procedure, then an oral exploration is made during which Decay and Periodontal Indexes are registered. Then the women are randomly assigned to receive the different types of fluoride varnishes or none, and another sample of saliva is taken. During that visit, the women are given advice about oral health and recommended for treatment. Then, there are second, third, and fourth visits after days 15, 30, and 45, and during those visits, another sample of saliva is taken, and, again, the different indexes are registered so we can see how these indexes change as a consequence of the program.

Intervention Type
Drug

Drug/device/biological/vaccine name(s)
Clinpro White Varnish 3M ESPE®, VOCO Profluorid Varnish®, MI Varnish GC Tokio®

Primary outcome measure
Fluoride concentration in saliva measured with a specific fluoride electrode, before the application of the varnish, immediately after, after 15 days, 30 days, and 45 days

Secondary outcome measures
1. Periodontal status, measured using the Community index of periodontal treatment needs (CPITN) over day 0, day 15, 30 and 45
2. Caries status, measured using the teeth with caries, absent because of caries or permanent teeth with fillings (CAOD) index over day 0, day 15, 30 and 45

Overall study start date
01/09/2018

Completion date
31/10/2022

Eligibility

Key inclusion criteria
1. Pregnant woman between 16 and 31 weeks of gestation
2. No abnormal syndromes found during gynecologist exploration
3. Willing to continue with the pregnancy
4. Pregnancy not classified as high risk
5. Acceptation of the informed consent
6. Pregnant women who speak and write the Spanish language properly
7. No mental disabilities

Participant type(s)
Healthy volunteer

Age group
Adult

Sex

Female

Target number of participants
80

Total final enrolment
89

Key exclusion criteria
1. Less than 15 weeks of pregnancy
2. More than 32 weeks of pregnancy
3. Abnormal syndromes found in the fetus
4. High-risk pregnancy
5. Women who have taken the decision to abort
6. Extreme difficulties to communicate
7. Patients with permanent orthodontic treatment

Date of first enrolment
01/09/2019

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
Spain

Study participating centre
Clínica Odontológica Universitaria - Universidad de Murcia
Avenida Marques de los Velez s/n
Murcia
Spain
30008

Sponsor information

Organisation
University of Murcia

Sponsor details
Paseo Teniente Floresta 5
Murcia
Spain
30003

+34 868 88 3000
3rciclo@um.es

Sponsor type
University/education

Website
https://www.um.es

ROR
https://ror.org/03p3aeb86

Funder(s)

Funder type
University/education

Funder Name
Universidad de Murcia

Alternative Name(s)
University of Murcia

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in a PhD Thesis and a high-impact peer-reviewed journal

Intention to publish date
30/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the privacy policy of the Universidad de Murcia

IPD sharing plan summary

Not expected to be made available